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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,519	06/22/2007	Dieter Manstein	036213/US/3 - 475387-290	1188

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DORSEY & WHITNEY LLP - NEW YORK
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EXAMINER	
BUCKLEY, AUDREA	

ART UNIT	PAPER NUMBER
1617	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)
	10/599,519	MANSTEIN, DIETER
	Examiner	Art Unit
	AUDREA BUCKLEY	1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 June 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-9,11,13,16,17,20-25 and 27-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-9, 11, 13, 16, 17, 20-25, and 27-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)	
1) ☒ Notice of References Cited (PTO-892)	4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) ☐ Notice of Informal Patent Application
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.	6) ☐ Other: _____.

DETAILED ACTION

Applicant's response dated June 14, 2011 to the non-final Office action of December 22, 2010 has been entered. Claims 2, 10, 12, 14, 15, 18, 19, and 26 previously were canceled. Claims 1, 3, 4, 11, and 27 have been amended, and new claims 31 and 32 were added; support for these amendments is found in the specification as filed.

Currently, claims 1, 3-9, 11, 13, 16, 17, 20-25, and 27-32 are pending and under consideration.

Withdrawn Rejections

The rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by Anderson et al. is withdrawn in view of Applicant's amendments to the claims filed 12/22/10.

The rejection of claims 1, 3, 4, and 6-9 under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. is withdrawn in view of Applicant's amendments to the claims filed 12/22/10.

The rejection of claims 5, 11, 13, 16, 17, 20-23, and 25 under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of Mueller et al. is withdrawn in view of Applicant's amendments to the claims filed 12/22/10.

The rejection of claim 24 under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. in view of Mueller et al. and Eppstein et al. is withdrawn in view of Applicant's amendments to the claims filed 12/22/10.

The rejection of claims 27-30 under 35 U.S.C. 103(a) as being unpatentable over Anderson is withdrawn in view of Applicant's amendments to the claims filed 12/22/10.

The rejection of claim 3 under 35 U.S.C. 112, second paragraph as being indefinite is withdrawn in light of Applicant's amendments to the claims 12/22/10.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3, 4, 6-9, and 27-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (US 2003/0159615 A1, filed Mar. 2003) in view of Yuzhakov et al. (US 6,565,532 B1, filed Jul. 12, 2000).

Anderson et al. teach permanent and removable tissue markings designed in advance for change and/or removal on demand; these markings are

implemented by applying specific energy such as electromagnetic radiation to the tissue marking site where colored microparticles have been implanted (prior to application of the electromagnetic radiation) (see abstract, in particular). Regarding claim 1, Anderson et al. teach that chromophores (see paragraphs [0087]-[0091]) are applied as tissue markings in the skin by implantation (see [0131], [0133], and [0136]). It is noted that this implantation process necessarily requires the application to a predetermined area of skin a specific pattern of fractional wounding as in the first method step of pending claim 1. Anderson et al. further teach the subsequent selective change and/or removal of these tissue marking microparticles can be applied (see [0044] and [0032]) by exposure to a specific type of electromagnetic energy (radiation) (see [0142]). Anderson et al. teach that this selective change is a pre-determined removal method which may be employed for changing or removing a tissue marking [0044]). The Anderson reference teaches that the inks can be implanted using a non-invasive method such as one which is well-suited to create an even tone of pigment over a relatively large body surface area (therefore, a layer) such as in the application of a removable sun tan (see [0132]).

Although Anderson teaches that the microparticles are deposited into the dermis to form part of a permanent tissue marking (see [0134], for example), it is not apparent that the particles are necessarily deposited into the epidermal layer, even though it would have been fractionally wounded for the application of the chromophores. Nonetheless, Yuzhakov teaches devices and methods for applying semi-permanent or permanent markings to skin or the subcutaneous

layer of the skin. Tattoo-like graphics (designs/patterns) can be applied or various skin structure modifiers can be delivered (see abstract, in particular). Depending on the embodiment of the invention, the marking material may penetrate the stratum corneum and epidermis but not the dermis of the skin in order to create a semi-permanent marking (see column 3, lines 55-60). Yuzhakov describes that for permanent markings, a dye may be injected into the dermal layer, and possibly beyond, where the microneedles which are the focus of Yuzhakov's invention, penetrate themselves only into the epidermis (see column 41, lines 55-63).

Anderson and Yuzhakov are both directed to tattoos created by damaging and implanting active agents into layers of the skin. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to select the dermal layer as the chromophore deposition site and would have been motivated to do so when a permanent tattoo was desired, based on the teaching of Anderson. Similarly, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to select the epidermal layer as the chromophore deposition site if semi-permanence or less pain was desired, based on the teaching of Yuzhakov.

As to claim 3, Anderson et al. teach that incomplete removal can be achieved by administering radiation to affect only a fraction of microparticles such as to reduce the color-intensity of a marking where the extent of photobleaching can be controlled by adjusting fluence per pulse and number of pulses administered (see [0158] and Example 3 [0173]). Because it is not certain that

Anderson et al. employed this method of fluence adjustment and pulse number adjustment, this rejection is made using obviousness rationale. Nonetheless, one reasonably would have expected continued success from the incomplete removal as adjusted by one of ordinary skill in the art as taught by Anderson. In addition, it would have been within the skill of the ordinary artisan to repeat the steps of incomplete removal for different components of the deposited chromophores, thereby removing a first portion first then applying radiation, as in the pending claim. One would have been motivated to do so in order to controllably alter the deposited chromophores in a manner consistent with the teaching of Anderson.

As to claim 4, Example 3 [0169] further teaches that the microparticular chromophores are prepared by grinding dry powdered Rose Bengal and sifting it to obtain uniform particles of a specified size to be implanted. Because it is not apparent that Anderson et al. implemented the powder as a dry powder, this rejection is made using obviousness rationale. However, since Anderson teaches the powder and the option to implement the powder as a suspension, it would have been obvious to one of ordinary skill that the suspension was not a necessary form for the powder implementation. Therefore, one reasonably would have had the expectation of continued success upon the implantation of the powder form of the microparticular chromophore (i.e., Rose Bengal as taught by Anderson).

As to claims 6-9, Anderson et al. teach coating materials which include substances capable of encapsulating chromophores such as cyanoacrylate and

Epo-Tek 301, an adhesive/structural glue, manufactured by Epoxy Technology, among others. Anderson et al. does not teach a particular embodiment of the invention employing Epo-Tek 301 (attachment medium, adhesive, glue); therefore, this rejection is made using obviousness rationale. Anderson et al. further teach that in some embodiments the coating is made of a material including specific absorption components that strongly absorb in a particular spectral region with the region from 800 to 1800 nm (light-activated) being most desirable [0080]). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to implement Epo-Tek 301, for instance, and/or a specific absorption component, in accordance with the teachings of Anderson. One would have been motivated to use Epo-Tek 301 in particular since Anderson teaches that these materials are biocompatible and approved by the FDA for use in medical devices (see [0121]), and one would have been motivated to use specific absorption (light-activated) components in order to control the release of the chromophores (see [0080]).

Further regarding claim 27, Anderson et al. teach that chromophores (see paragraphs [0087]-[0091]) are applied as tissue markings in the skin by implantation (see [0131], [0133], and [0136]) and that the subsequent selective change and/or removal of these tissue marking microparticles can be applied (see [0044] and [0032]) by exposure to a specific type of electromagnetic energy (radiation) (see [0142]). It is noted that this implantation process necessarily requires the application to a predetermined area of skin a specific pattern of fractional wounding. Anderson et al. teach that this selective change is a pre-

determined removal method which may be employed for changing or removing a tissue marking [0044]). Anderson et al. explicitly teach that the inks can be implanted using a non-invasive method such as one which is well-suited to create an even tone of pigment over a relatively large body surface area such as in the application of a removable sun tan (see [0132]). Further, Anderson et al. teach that incomplete removal can be achieved by administering radiation to affect only a fraction of microparticles such as to reduce the color-intensity of a marking where the extent of photobleaching can be controlled by adjusting fluence per pulse and number of pulses administered (see [0158] and Example 3 [0173]). As to claim 27, this teaching indicates that one of ordinary skill in the art at the time of the invention would have been able to apply the tissue markings in a selected pattern (thus, simultaneously not applying tissue markings or generating a thermal injury in at least a portion of the predetermined area).

As to claims 28 and 29, Anderson et al. does not specify the exact instantly recited dimensions.

Nonetheless, the Anderson reference indicates that the microparticles (equal to or including the chromophore) have a radius between 50 nanometers and 100 microns (see [0027] and [0028]). Since the area of affected tissue corresponds to the contacted chromophores, the area of thermally or radiatively damaged skin would have correlated to the chromophore size. This particle size range overlaps with the approximate 1-1000 micrometer dimension range of claim 28 and the approximate100-800 micrometer dimension range of claim 29. MPEP 2144.05 says that in the case where the claimed ranges “overlap or lie

inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to utilize microparticles sized as taught by Anderson and to subsequently optimize the microparticle size in order to control inflicted changes to the exposed tissue. One would have been motivated to do so since the Anderson reference teaches that exposure to the specific energy results in the controlled release of the colored microparticles (chromophores) in the pattern of chromophore deposition (see [0028]).

As to claim 30, Anderson teaches that skin injury is extremely local (see [0012]) and indicates that the light pulses are controlled with little or no absorption by surrounding tissue. Regarding the distance between damaged tissue regions as in pending claim 30, it is the Examiner's position that this spacing feature is a result effective variable which depends on the chromophore/particle pattern of distribution as applied by the artisan. That is, the spacing feature of pending claim 30 is a result effective variable because changing it will clearly affect the type of product obtained. See MPEP § 2144.05 (B). Case law holds that "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." See In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). In view of this, it would have been obvious to one of ordinary skill in the art to utilize appropriate spacing distances between thermally damaged regions of tissue, including those within

the scope of the present claim, so as to provide the desired end results of the predetermined tissue application of chromophores/particles.

As to claims 31 and 32, one of ordinary skill in the art at the time the invention was made reasonably would have expected success from further applying the thermal damage to the dermal portion of the skin, in addition to the epidermis, based on the combined teaching of Anderson and Yuzhakov. One would have found it *prima facie* obvious and would have been motivated to do so to reinforce the temporary nature as well as the permanent nature of the pattern applied.

Claims 5, 11, 13, 16, 17, 20-23, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (US 2003/0159615 A1, filed Mar. 2003) in view of Yuzhakov et al. (US 6,565,532 B1, filed Jul. 12, 2000) as applied to claims 1, 3, 4, 6-9, and 27-32 above and further in view of Mueller et al. (US 5,836,998, patented Nov. 1998).

The teachings of Anderson et al. are delineated above. Anderson et al. teach that the microparticles can be used to produce new cosmetic markings by addition to the tissue of and/or under the fingernails, for example, to create solid colors, patterns, or designs for decorative purposes [0138].

As to claims 5, 13, and 17, Anderson et al. do not teach the devices (i.e., stencil) for application as instantly recited. As to claims 11 and 16, Anderson et al. do not teach the application of a mask with a pattern where the pattern corresponds to the desired “fractional wounding” pattern.

However, Mueller et al. teach a stencil for body art wherein the stencil allows a decorative stain to be applied to a predetermined epidermal area (see column 1, line 65 – column 2, line 11). As to claims 16 and 25, see Figure 1 in which the stencil design (a heart shape) allows for the application of color (chromophore) where the skin is not in contact with the mask.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to implement the stencil pattern as taught by Mueller et al. for improved control of the chromophore application/removal pattern in the methods of Anderson et al. One would have been motivated to do so in order to minimize human error and to maximize control over the product design in its application, as taught by Mueller et al. (see column 2, lines 9-10).

As to claims 20 and 21, Anderson et al. teach chromophores including modern pigments of inorganic metal salts and brightly colored organometallic complexes [0006] which necessarily would act as chromophores, reflecting light and colors. Also, Anderson teaches silica and glass light reflectors as chromophore components Bis(diiminosuccino-nitrilo)metal complexes and silica are an example of these chromophores (see Anderson claim 35, for instance). Based on this teaching, one of ordinary skill in the art reasonably would have expected continued success from the implementation of the metal complex or silica chromophores taught by Anderson.

As to claim 22, it is noted that Anderson et al. teach graphite (carbon) and carbon among the chromophore components (see [0023]) where graphite in particular is named among the examples of useful colored near-infrared

absorbing materials [0095]). Anderson's Example 1 employs graphite particles in the chromophore microparticles (see [0162]). As to claim 23, it is noted that Example 2 of Anderson teaches that yellow microparticles are ruptured by IR radiation (heat) (see [0165]). Therefore, Anderson teaches a yellow chromophore that undergoes a phase transition upon a change in temperature. As to claim 23, Anderson teaches that the chromophore may be thermolabile such that exposure of the microparticle to the specific energy heats and alters the chromophore (see [0023]). Based further on the teaching of Mueller et al, one of ordinary skill in the art at the time the invention was made would have expected continued success upon implementing the chromophores of Anderson et al. in various embodiments of the invention.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (US 2003/0159615 A1, filed Mar. 2003) in view of Yuzhakov et al. (US 6,565,532 B1, filed Jul. 12, 2000) and Mueller et al. (US 5,836,998, patented Nov. 1998) as applied above, and further in view of Eppstein et al. (US 2002/0091311 A1, published Jul. 2002).

The teachings of Anderson et al. and Mueller et al. are delineated above.

As to claim 24, Anderson et al. teach waxes with a melting point substantially above body temperature (i.e., paraffin), for example, natural waxes, synthetic waxes, and mixtures, (see [0079] and [0113]). However, neither Anderson et al. nor Mueller et al. teaches any paraffin in particular.

However, Eppstein et al. teach methods for transporting substances across a biological membrane of an animal such as a human where openings in the biological membrane facilitate treatment applications, et cetera. Specifically, Eppstein et al. teach that the substrate may be designed to deliver pigments to effect an instantaneous tattoo application upon detonation of the pyrotechnic charges suitable for veterinary or cosmetic tattoos. The substrate may preferably be chosen from the suitable examples including paraffin, waxes, and other functional equivalents (see [0002] and [0044]).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to utilize paraffin in particular as taught by Eppstein et al. for the wax generally disclosed in Example 1 of Anderson et al. From this substitution of equivalents known for the same purpose, one of ordinary skill in the art at the time the invention was made reasonably would have expected continued success (see MPEP 2144.06) and would have been motivated to make this substitution since paraffin is a particular suitable material more specific than "wax" and explicitly taught to be useful for containing pigments for cosmetic tattoos (see [0044]).

Response to Arguments

Applicant's arguments presented 12/22/10 have been fully considered but are not persuasive in view of the claim amendments filed therewith. As noted above, all rejections previously presented and not re-iterated herein are

withdrawn. Applicant's positions against the cited references are summarized and responded to as follows.

Applicant argues that the Anderson reference, taken either alone or in combination with the Mueller and Eppstein references does not teach the claimed invention. Applicant underscores that the Anderson and secondary references do not teach the claim amendment which requires that the thermal damage happens in at least an epidermal portion of the skin. In reply, this position has been fully considered but is not persuasive in view of the new grounds of rejection, presented above, which were necessitated by this amendment. The Yuzhakov reference, as applied above, addresses this limitation.

Applicant "re-asserts" that the Anderson publication "teaches away from such subject matter", however this position has been addressed previously. Applicant asserts that the Mueller patent is not able to be combined with the Anderson publication, however this position is not substantiated by evidence and does not appear to consider the level of skill of the ordinary artisan. As such, Applicant's position is not persuasive.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**.

See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AUDREA BUCKLEY whose telephone number is (571)270-1336. The examiner can normally be reached on Monday-Thursday 7:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydoun Sajjadi can be reached on (571) 272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/AJB/

/RICHARD SCHNIZER/
Primary Examiner, Art Unit 1635